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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,764	11/14/2005	Filippo Bastia	38328	9211
116 7590 09/27/2007 PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			EXAMINER KASZTEJNA, MATTHEW JOHN	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 09/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/540,764

**Applicant(s)**

BASTIA ET AL.

**Examiner**

Matthew J. Kasztejna

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/7/7</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Notice of Amendment***

In response to the amendment filed on September 7, 2007, canceled claims 1-26 and new claims 27-51 are acknowledged. The following new grounds of rejection are set forth:

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Applicant refers to a "means for reflecting the light" and "reflecting means". Applicant is advised to ~~use~~ consistent terminology when referring to reflecting means. Appropriate correction is required.

*Handwritten:*  
9/20/07

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim 1 recites the limitation "lateral window" in line 11 of the claim. There is insufficient antecedent basis for this limitation in the claim.

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Claim 1 recites the limitation "conjunction zone" in line 12 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 30, 36 and 39 recite the limitation "reflection parabola". There is insufficient antecedent basis for this limitation in the claim.

Claims 30-32, 35 and 38 recite the limitation "reflecting parabola". There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "connecting zone" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 34 recites the limitation "connecting portions" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 37 recites the limitation "lateral window" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "parabola" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 40-44 recite the limitation "exploration window" in line 1 of each of the respective claims. There is insufficient antecedent basis for this limitation in the claim.

Claims 45-46 recite the limitation "receiving and centering means". There is insufficient antecedent basis for this limitation in the claim.

Claim 48 recites the limitation "longitudinal opening" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 27 and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by EP 1,234,539 to Gmbh.

**In regards to claims 27 and 40-44**, Gmbh discloses a disposable device for surgical operations on the arteria haemorrhoidalis (FIG. 1) comprising a retractor tube closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1), a gripping handle; means to illuminate said window (light guide 10 in FIG. 2), said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (see. FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1). The arrangement also has a proximal region (3) where the hand grip is located, and a distal region (4) containing an ultrasound probe (6) for localizing an artery and an opening (7).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,234,539 to Gmbh in view of FR 2,623,078 to Gilles.

**In regards to claims 28-39**, Gmbh discloses a disposable device for surgical operations on the arteria haemorrhoidalis (FIG. 1) comprising a retractor tube closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1), a gripping handle; means to illuminate said window (light guide 10 in FIG. 2), said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (see. FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1). Gmbh is silent with respect to a specular parabola. Gilles teach of an analogous apparatus wherein a mirror is used as means to reflect light in a (see page 3, lines 29-32). The choice of a parabolic mirror as a specifically formed mirror comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. It would have been

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obvious to one skilled in the art at the time the invention was made to include a parabola in the apparatus of GmbH, to distribute light more efficiently within the device as taught by Gilles.

Claims 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,234,539 to GmbH in view of U.S. Patent No. 5,570,692 to Morinaga.

**In regards to claims 45-51**, GmbH discloses a disposable device for surgical operations on the arteria haemorrhoidalis (FIG. 1) comprising a retractor tube closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1), a gripping handle; means to illuminate said window (light guide 10 in FIG. 2), said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (see FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1). GmbH is silent with respect to a curved needle being located inside of the retractor tube under an exploration window. Morinaga teaches of an analogous device comprising an ultrasonic doppler blood flow detector used for hemorrhoid artery ligation having a hollow insertion cylinder which is enclosed at the distal end and open at the near end, and can be inserted through the anus; the cylinder has an ultrasound transducer in its interior wall, for detecting blood flow in the affected artery, and a ligation hole next to the transducer, through which the detected artery is ligated with

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ligation device, such as a curved needle or a wire for cautery (see Figs. 1-3). It would have been obvious to one skilled in the art at the time the invention was made to include a curved needle in the apparatus of GmbH, to effectively treat diseased tissue as taught by Morinaga.

### ***Response to Arguments***

Applicant's arguments with respect to claim 27 has been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK



9/20/07



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